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NOV 4 2002

SECTION P - 510(K) SUMMARY

Trade Name:	HemCon™ Bandage
Device Class:	Class 1
Classification Panel:	878 - General and Plastic Surgery
Common Name:	Traumatic Wound Dressing
Classification Name:	Bandage, Liquid
Predicate Devices:	RDH Bandage, Marine Polymer Technologies 510(k) # #K002550 SyvekPatch®, Marine Polymer Technologies 510(k) # K972914
Submitted by:	James F. Hensel, President
Company Name:	Hemcon, Inc.
Company Address:	10575 SW Cascade Ave., Suite 130 Tigard, OR 97223
Company Telephone:	503-245-0459
Company Fax:	503-245-1326
Prepared On:	October 1, 2002

The HemCon™ Bandage is intended as an external temporary wound treatment for the control of severely bleeding wounds for emergency use. In addition, the HemCon™ Bandage also controls bleeding in patients following hemodialysis.

The HemCon™ Bandage is applied to the wound and held in place until it adheres to the wound and hemostasis is achieved. Then, an outer bandage is applied to secure the dressing on the wound site.

The HemCon™ Bandage is manufactured from ChitoClear™ chitosan ,a material consisting of cellulosic polymer, poly-*N*-acetylglucosamine. This formulation has been self-affirmed by the manufacturer as a GRAS (Generally Recognized as Safe) food ingredient in accordance with 21 CFR § 170.30. Several biomedical applications of chitosan have already been reported. The GRAS Report provided by the supplier refers to safety studies in human beings and several species of animals. The studies cited represent research on the safety and use of chitosan, which have been published over a period of decades by scientists from around the world. This large body of scientific literature satisfies the requirement in 21 CFR § 170.30 (a), that a general recognition of safety requires common knowledge about the substance throughout the scientific community.

Chitosan has many advantages due to its nontoxicity and biodegradability without damaging the environment. It is a biocompatible material that breaks down slowly in to a harmless product, glucosamine, that is absorbed completely by the body. Please see the reference list provided.

This device is packaged in a foil package and is provided sterile. It is sterilized by gamma irradiation at 15 kGy ensuring a SAL of 10^{-6}. The validation study conducted

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according to ISO 11137, Method I is on file at Hemcon. Labeling has been provided in this application.

The HemCon™ Bandage has been tested in several settings utilizing accepted and approved animal models of hemorrhage and compared to existing hemostatic control products. The HemCon™ Bandage out-performed the gauze control in all criteria. There was no statistical difference in the pre-injury animal characteristics. The HemCon™ Bandage exhibited a lower rate of post treatment blood loss, a reduction in fluid use, and a higher rate of survival and hemostasis.

The HemCon™ Bandage is similar to Marine Polymer Technologies' RDH Bandage™ and SyvekPatch® in intended use, indications, material, performance, sterilization method, and method of application. In summary, the HemCon™ Bandage is expected to achieve the same safety and effectiveness as the predicate devices mentioned above. Predicate device comparison tables are included in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 4 2002

Hemcon, Inc.
James F. Hensel
President
10575 SW Cascade Avenue, Suite 130
Tigard, Oregon 97223

Re: K023298
Trade/Device Name: HemCon™ Bandage
Regulation Name: Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 2, 2002
Received: October 3, 2002

Dear Mr. Hensel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION T - STATEMENT OF INDICATIONS FOR USE

INDICATIONS FOR USE

Applicant: Hemcon, Inc.

510(K) Number (if known): Not Yet Assigned

Device Name: HemCon™ Bandage

Indications for Use:

HemCon™ Bandage is a hemostatic dressing for the external temporary control of severely bleeding wounds intended for emergency use. In addition, the HemCon™ Bandage also controls bleeding in patients following hemodialysis.

(PLEASE DO NOT WRITE BELOW THIS LINE- -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023298

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-9